

Governance Workgroup
Draft Transcript
November 15, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good afternoon, everybody, and welcome to the Governance Workgroup. This is a Federal Advisory Committee, so there will be opportunity at the end of the call for the public to make comment, so let me do a quick roll call. John Lumpkin?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

John Glaser? Laura Adams? Leslie Harris? Christine Bechtel or Eva Powell? John Mattison?

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Linda Fischetti?

Linda Fischetti – VHA – Chief Health Informatics Officer

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Michael Matthews?

Michael Matthews – MedVirginia – CEO

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

John Houston?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Carol Diamond? She's joined. Wes Rishel? Tim O'Reilly? Mary Jo Deering?

Mary Jo Deering – ONC – Senior Policy Advisor

Present.

Judy Sparrow – Office of the National Coordinator – Executive Director

Elliot Maxwell?

Elliot Maxwell – ONC – Expert Contractor for Health IT

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Melissa Goldstein?

Melissa Goldstein – Dept. of Health Policy – Associate Research Professor

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Did I leave anybody off?

Mariann Yeager – NHIN – Policy and Governance Lead

Mariann Yeager is here.

Judy Sparrow – Office of the National Coordinator – Executive Director

With that, I'll turn it over to John Lumpkin.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Good afternoon and thanks, everyone, for engaging in what has been a very rapid run towards the meeting later this week on Friday. We've had a very detailed and, I think, fruitful discussion, both in the meeting on—whenever it was—Wednesday, and some follow up conversations. Once again, I'd encourage, as I mentioned in my last e-mail, encourage people to make comments on the modifications that we've made since the last call. As we work towards issuing our report to the HIT PC on Friday, we have one additional call on Wednesday, and then we will prepare the report for delivery.

Today, I'd like to try to get to the area that we did not get to, which is the validation role, to have some conversation about that, and if we have any time left over today, we can go back and discuss modifications. If not, we will focus the initial portion of our next call on the modifications and the overall report. Any questions before we go ahead? Okay.

If we can start walking through the slides, I'm going to jump ahead to slide number seven. On this particular slide, I just want to call your attention, although we may or may not have opportunity to do that, there were a number of questions raised on— That's not the slide seven I have. Why don't we go ahead to nine? That's correct. Thank you.

There was a fair bit of discussion about the issue of coordination, whether or not that was the right word, so we've come up with the idea of what we were talking about as operations and implementation as being that sort of central function. So the role there being to play a harmonization role between the policies for implementation and groups in exchange communities or modes of exchange. That's one of the aspects, so please take time, if you haven't had an opportunity read through this and submit comments to me by e-mail so that we can incorporate them into what we will be discussing on Wednesday.

In the next slide, you'll see again that we talked about gaps. It remains pretty much unchanged. When we boiled that down, we talked about the three roles being implementation and orientation, so again taking a look at that slide, which is now slide 11. Moving ahead, we're going to go now all the way to what I believe will be slide number 21, 22.

Mary Jo Deering – ONC – Senior Policy Advisor

John, on slide 12, there was a high level discussion about the attributes of the validation

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Thank you very much. Let's go back. Yes, let's do that. Slide number 14 then. Right. Once again, as we talked about at prior meetings the three areas that we're looking at are the federal role, implementation and operations, and then the third one being the validation role. That in order to engender trust, we need to create an environment where one party that's engaging in exchange with the other party will have some belief that that other party is adhering to the policies and standards that established that essentially make up the Nationwide Health Information Network. The attributes that we

believe should be part of the validation roles should be first that the sufficient authority for results be binding to authorize, deny, or revoke this validation and that there should be subject to appeal mechanisms, due process, etc. That we would expect that this validation entity would have expertise in the domains that would be validated and where appropriate, would leverage existing mechanisms.

We would expect that there would be strong coordination with the federal government and the implementation entity or entities. In this particular instance, much of its authority would be generated based upon a delegated authority from the federal government. That the validation role would be objective and a repeatable process so that people believe that they're being treated fairly if they're being assessed with minimization of the amount of paperwork, so it's efficient and effective, being able to scale on a national level. Then finally that we would expect that the attributes of a validation role would be that appropriate management and operation of the validation activity. Any questions on this slide before we move on?

I think—Mary Jo, help me, unless I'm wrong—we can skip now to 22.

Mary Jo Deering – ONC – Senior Policy Advisor

I think that's right.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

This is the description of the validation role. This, again, as we've done with the other ones, this is what we're setting up as the candidate recommendation. The first is that there should be a recognized Nationwide Health Information Network validation entity or entities to verify that conditions for participation established by the Office of the National Coordinator are met as a precondition to exchanging through the Nationwide Health Information Network or using the Nationwide Health Information Network brand. Why don't I stop there and see if there are comments about this proposed recommendation. This is the high level one.

Hearing none, let's talk a little bit about the responsibilities. This entity would have the responsibility to apply, establish applicable eligibility criteria to determine who is eligible for participation, verify the systems used to exchange meet the technical requirements, allow other equivalent certification and validations processes to satisfy the validation, what's called in other areas as being deemed status. So if it's certification for an electronic health record or state HIE certification, that those would be considered to be equivalent and acceptable by the validation entity. That they would verify in these practices are then consistent with an applicable nationwide HIN policies, and those would be the ones that would not have already been deemed to be equivalent. Then to investigate non-conformance with the conditions of participation and take remedial action, including revoking participation, and have a process for appeals.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

A couple points: I think the first one is that the second bullet point, verify systems used to exchange the NHIN meet the technical requirements, I am sure that over the many years that we hope that NHIN will be in operation that customers will have or the participants will have a variety of solutions, and many of these systems will be quite complex. I'm just wondering whether that is necessarily that important to verify systems or that we simply get a certification from the participant that they will use systems that meet technical requirements. That's my first point. I don't know if you want to respond to that.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Yes, let's hold on to your other points, if you can, and see if there are any comments on that response. Is it safe to assume that the lack of comments is that people agree with John Paul?

M

Could you please just restate it, John?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

John, can you restate that?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I'm just concerned that this notion of actually verifying specific systems that participants would use is something that's going to, in essence, get out of date very quickly that over the hopefully the long life that NHIN will exist that participants will have a variety of solutions over time that maybe be replaced, may even involve multiple systems. I think what's probably more important is that there simply be a requirement that participants certify that their systems meet the technical requirements rather than some other verification.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Would that include for privacy for security?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I think so. I think self-certification is probably, yes, a great model in both cases.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Okay. So your proposal would then be that we would replace that with self-certification for the technical requirements?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Comments?

M

A clarification question: Is that intended to be self-certification after the initial external certification so that it's only to upgrades that are self-certified as opposed to the original is externally validated?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

I'm just not sure whether there's much value to having somebody validate an initial system to begin with. To me, the governance portion of this is more important to make sure that the entity is—what's the word—that they should be participating. Getting into verification of systems, to me, just seems like you're getting into the weeds at a level that's not really meaningful.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Other comments?

Mariann Yeager – NHIN – Policy and Governance Lead

Just to kind of clarify, I think, some of the rationale for why it was originally included was since one of the overarching objectives for the NW-HIN is that it meet a level of trust and interoperability that there may be some instances where it's important to test and know that the systems and interfaces used for the exchange do in fact meet a level of conformance to underlying standards and specifications. That's primarily to assure interoperability. That it was something that was identified as fairly core up front and something, I think, goes hand in glove with some of the other recommendations, for instance, around meaningful use, that there'd be some sort of system certification or testing to know that there's some level of interoperability.

M

But for meaningful use, a lot of that is—I was under the understanding that it was really self-certification in that case as well.

Mariann Yeager – NHIN – Policy and Governance Lead

Right.

M

So that seems to me the same paradigm that you're going to do self-certification. I look at this in terms of interoperability is just like when the standard transaction sets were first proposed, and people had a test. There was a lot of testing that would go on, but ultimately the result was the desire to end, or the result was that by through testing and the like, people could actually make or pass standard transactions in a form that was readable to both sides.

Mariann Yeager – NHIN – Policy and Governance Lead

The distinction here again is, as I understand it, the conditions of participation, which would include technical requirements, should exist to provide confidence that information can be exchanged in a way that's, I guess, usable, interoperable, and trusted. The question is, can you have interoperability without some authoritative way to test that the information being exchanged is being done in a way that is truly interoperable. Is it enough just to take someone's word? Is that enough for folks to agree to exchange data? There are several folks on the governance workgroup that could probably speak to this more directly about whether testing and having some assurance that the data being exchanged is actually interoperable rather than taking someone's word for it, if that would be sufficient.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Other comments? What do they do under the DURSA?

Mariann Yeager – NHIN – Policy and Governance Lead

Michael Matthews, I don't know if you want to speak to it, but there is actual validation, technical validation that is required. It is both conformance testing to make sure that the party is exchanging data in accordance with the standard in a way that's complying with the standard. But there's also interoperability testing to make sure that the data being exchanged actually can be used by the system that received it and interpreted and applied the same way. It's probably one of the most important parts of the process around the exchange today. The DURSA points to the validation plans and the specifications and requires compliance with both of those, but I think others can speak to that as well.

M

But is that validation done by the participant or by some validating entity?

Mariann Yeager – NHIN – Policy and Governance Lead

It's both. Their participant ideally would have access to testing utilities that are publicly available. They're looking at some of the tools that NIST has to make sure that there's equivalency there, so some of it is self-testing and providing evidence that the systems can meet conformance. It is also facilitated by an independent, third party, a testing, a validation entity that facilitates that.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

I think what we may be stumbling upon here is the difference between the startup of a NW-HIN versus the long-term sustainability. So the self-certification model makes a lot of sense to me in the end game, but in the start up, our experience has been that this validation process is incredibly valuable in having both the self-certification between participants, as well as an oversight mechanism for adjudication is pretty essential. Maybe what we can do is do some offline crafting of language that distinguishes the startup phase from a long-term phase and establish criteria for when we might migrate from a more rigid process to a more purely self-certified process because I agree with the suggestion about the virtues of self-certification once there's a certain level of stability in the system. But I think, right now, we're still at a phase where we need to have some pretty significant controls to create that stability.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Other comments?

Linda Fischetti – VHA – Chief Health Informatics Officer

John, I agree with your statements in terms of how valuable is a startup. Let's not be proscriptive as to what the NHIN governance group will do once they know what they don't know today, as they get out of startup. John Paul, are you comfortable if we leave the statement as it is, and then maybe put something on there such as the NHIN governance entity can do an assessment as to whether this is useful or it needs to do something different or more efficient in the future, as it learns what it needs to proceed?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

That's fine.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Linda, that makes a lot of sense to me.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Great. Thank you, all. John Paul, second point?

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Second point, being also on the Privacy and Security Tiger Team and some of the discussions we've had over the last couple days about granting credentials, I'm not sure whether it goes on this slide 22 or somewhere else in the presentation, but one of the points I made in that group was that we needed to make— We didn't want to be doing similar types of activities between the two committees or making similar recommendations between the two committees that were somewhat in conflict or at least not completely harmonized. One of the things that, as I said, they wanted to do was discuss how credentials would be provided or not credentials, but I'm missing the word. Yes, credentials, I guess, how they would be issued. I think that part of this committee maybe in this slide as well would be also to help provide the credentials that are necessary to securely pass transactions through the NHIN, if that makes sense.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

If we could then perhaps suggest that we would put in the language that recognizes the work of the tiger team and suggests that our recommendations need to be harmonized.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Yes. Again, I think that the key area is that they want to issue credentials for passing information. Through all this process of validating roles and doing this and doing that, I think part of this would be that this governance group could also issue those credentials or be the organization that ultimately issues their credentials in satisfaction of the recommendation of the tiger team.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Right.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Is Mary Jo Deering on the phone?

Mary Jo Deering – ONC – Senior Policy Advisor

Yes, I am, John.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

Does that make sense of what we talked about on Friday?

Mary Jo Deering – ONC – Senior Policy Advisor

I think it does. One of the things you may know is that we set up a call between Paul and Deven and John Lumpkin at 5:00, and I think we can go into that. I guess I would welcome your participation on that call, if you're free. John Lumpkin, we have a specific slide here from the tiger team that you haven't seen yet that sort of tees up this question. I think we can take it offline. The bottom line is, we do need to

synch up, but it was pretty clear from the tiger team's perspective, they're actually doing a hand off of us just recognizing, and so

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

... I think it was my recommendation to make the handoff, so

Mary Jo Deering – ONC – Senior Policy Advisor

Yes, so I think we will need to do just a little bit of fine-tuning here, but in principle, everybody wants to go there.

John Houston – Univ. Pittsburgh Medical Center – VP, Privacy & Info Security

That was my only other comment.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Any other comments on the slide 22, the points on slide 22? Let's move on to slide 23.

Michael Matthews – MedVirginia – CEO

John, earlier you had the term exchange communities and also incorporated implementation groups. Some of the language here looks like it's a combination of individual members of the exchange communities, and some of it looks like the exchange communities themselves. The validation piece looks like the individual entities within an exchange community, and so I'm confused about what the validation is. Is it really NW-HIN that's going to do validation of individual members are in an exchange community? I thought that was the role of the exchange community to validate its members consistent with the policy standards that's NW-HIN.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Let me just give a little bit of background, and so I'm going to suggest we kind of play around with language a little bit and then ONC can figure out exactly what they want to use. A practice may choose to exchange as an individual entity, or they may be a member of an implementation group that could look like an HIE. That groups of HIEs may be in an exchange community or other organizations that exchange in a similar kind of fashion. As I understand what we're recommending—and we'll just need to check the language again—is that it would be the responsibility of the implementation group to validate their members and that the validation process we're talking about is the validation of those implementation groups, whether that be NHIE or some other kind of entity that is supporting exchange within an identified group of players. Is that what other people understand?

M

Yes.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Michael, does that answer your question?

Mary Jo Deering – ONC – Senior Policy Advisor

I just want to say that on the town hall meeting where there was a roundtable discussion that I had today that unfortunately the dial in number didn't end up working very well, I think this is an area where there's probably going to need to be a little more thought. They too immediately went to this issue of how are we defining entities and who touches those entities. I know that the tiger team is doing this too. I don't believe that the workgroup has really had a thorough discussion of the implications of that. I know certainly we think that we at ONC still have some thinking to do for ourselves, and would look forward to your help on that. So this could be an area where once we get it down, we realize that there's another aspect to it. We might request the ability to come back to you in a more focused way maybe if we can tee up a specific question that would get at what could conceivably be a gap in our thinking here. Maybe not, but I do just want to sort of put on the table that it occurred to us that there's unfortunately devilish details

in this area of what is an entity and who touches the entity are really very profound, and we haven't had the time to get into as much detail as we'd like.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Let me just sort of touch that aside. We, as a workgroup, have agreed that what we're going to do is deliver a report at the end of the week. Then after the NPRM to solicit comments and then issue comments on the NPRM. There is, as Mary Jo just stated, the potential for ONC to come back to us between the time when we issue our report and the NPRM to ask some very discrete questions. At that point, we would then, if that does become a reality, we would solicit the willingness of the workgroup to participate in that activity. Given that, I think, if we're comfortable right now that we would expect that the implementation group would be engaged in the validation process. If there's a validation entity, they may choose to use that same validation entity. But that what we're talking about within the range of governance is validating those parties that are exchanging as part of the Nationwide Health Information Network. In other words, agreeing to adhere to the policies and standards that by being an implementation group, and HIE or whatever, that part of the expectation in that validation would be that they are assuring that there are policies and standards that are being adhered to by the individual entities within that implementation group that are exchanging.

Elliot Maxwell – ONC – Expert Contractor for Health IT

John, does that assume that every entity that holds itself out as a participant is going to be in an implementation group?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

No.

Elliot Maxwell – ONC – Expert Contractor for Health IT

Because there may well be small entities where there's, as in financial services, different forms of validation taking into account the nature and scale and competencies of the participants.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

That would be correct. So let's say a private practice in a rural community in North Dakota may not have an HIE, but the three or four docs and the nurse practitioners and physician assistants working there may choose, as a group, to participate, in which case they would go through validation, as we're discussing. Are we comfortable with that? Can we move on?

Michael Matthews – MedVirginia – CEO

John, this is the essence of the entire discussion over the last two months is, I'm with you almost. The implementation group will validate its members, and the implementation groups themselves are validated by the NW-HIN governance. To Elliot's point, then there are entities out there that would not identify themselves as being representative of an implementation group, but the collective of them in fact would be part of the NW-HIN, and so would be looked at as part of that overall community. If they're to be governed, they need to be governed, and so the governing body over these individual members would be NW-HIN. Therefore, they are represented as part of that group.

The ... around this, if we can't get it straight within our group that's spent hours and hours and weeks and months on this thing, I just think we're introducing too much ambiguity into the process if we don't sharpen our language around this. So I like what you just said. I think this issue of the one practice in rural South Dakota or wherever it was that we were referencing connecting in, I think we ought to have some language around what that looks like, what it means, and be able to accommodate that visually, linguistically in terms of incorporating that into our overall model and structure\.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Other comments?

Mary Jo Deering – ONC – Senior Policy Advisor

I just want to say I absolutely agree, Michael. I think that was the confusion that people were raising in this roundtable this afternoon too, and that's what I meant meaning to just chew on this a little bit because we haven't been able to really describe it accurately yet, even though I think we all instinctively sort of come to accept it as just a reality, so thank you for that reminder.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

I'm going back to one of our previous slides. So if I could go back to slide number 14, which actually should be slide 16, sorry, that we talked about, and this was reframed based upon our discussion that there should be a universal set of required conditions of participation that applies across all scenarios that there may be others that apply in certain circumstances based upon particular functions, and that there would be a mechanism to waive these conditions of participation. That would mean that if you take that construct and apply it then to validation that they are actually performing these conditions of participation, that gives you the flexibility to deal with an entity that is a practice in a remote area that wants to exchange, an implementation group that would be a group of practices in a community or even a state, such as an HIE, and would have the flexibility based upon a flexible structure of conditions of participation. Does that help reduce some of the ambiguity?

Elliot Maxwell – ONC – Expert Contractor for Health IT

Since I might have contributed to it. Let me suggest that one of the ways of dealing with this is a little bit in the nature of a punt. The word validation can have a multitude of meanings, as we've seen in the slides that we've gone over in the past. It may be that you want to make sure that the notion of validation is there and lead to subsequent activity, partly the rulemaking, partly the operation of the governance entities themselves, specification as to the level of validation that would be utilized in different circumstances with different entities, as long as it's clear that the validation will take place, but without the need to specify the level of validation and the appropriate mechanisms for doing it, given the range of entities that will be participating.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

If we could go to slide 22, then we could say, in the high level— Okay. In our high level statement, we say there should be a recognized validation entity or entities that verify conditions for participation established by ONC. So that means it's not necessarily a standard set of conditions of participation. What we should be saying maybe is applicable conditions of participation. That would be the key that we have to look at what this entity is before you begin to apply the test. Does that work for folks?

We move on to 23. As we've just gone through, we've actually talked about the components of this. I'm going to suggest we take a look at this particular slide and move on looking at the clock to slide number 24. So the options then are either that for ONC to delegate authority to an overarching validation authority, which would have responsibility to accredit validation entities, much like the process being done with the EHR certification. That would also establish equivalency criteria and establish and recognize other non-accreditation approaches and monitoring them to insure coordination and consistency with established conditions of participation. That's one option.

The second option is that it delegates authority for specific certification accreditation activities only, and then the other validation activities retains authority to make sure the objectives are met in ONC. Then the third one is that ONC just creates one single entity, so essentially the second option is a mixed option between A and C. Do we have preferences amongst this group, or is there an option that should be on the table that's not included? Anyone out there?

W

We're here.

W

Mary Jo, do you have any insight into the spirit of HITECH on this, or is it really just that one sentence with no spirit behind it?

Mary Jo Deering – ONC – Senior Policy Advisor

The spirit resides in the workgroup that is a subcommittee of the FACA that was established by HITECH that put a single line of guidance in.

W

Got it.

Mary Jo Deering – ONC – Senior Policy Advisor

You are the medium, media through whom the HITECH intends to channel at this point.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Since I haven't heard anybody, I'm going to toss my hat at A, and I will say that that seems to strike me as the system that has the most flexibility, allows for essentially the market to create different pathways and doesn't create as much of a log jam as a single entity that tries to do everything. Now all of you are stuck with either having my say go or make a comment. Who is trying to get in?

Linda Fischetti – VHA – Chief Health Informatics Officer

I guess I was leaning towards simplicity, but it would be a lot better if we had a crystal ball and we knew exactly how this would play out. Your statement of logjam resonates.

Mary Jo Deering – ONC – Senior Policy Advisor

But, Linda, I'm just curious. If you were leaning towards simplicity, what is that? What did that mean? Did that mean B or C? You went back on mute, Linda.

Linda Fischetti – VHA – Chief Health Informatics Officer

Sorry about that. I'm not sure. Possibly, B is the hybrid of the two, correct?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Of a sort.

Mary Jo Deering – ONC – Senior Policy Advisor

B is, I think you could also say it's simply narrower also. It's a little more minimalistic. It says that we are only going to be concerned about certain critical aspects, and that's what we will establish certification and accreditation for. Everything else, we are going to just sort of monitor the environment or wait for complaints and take action later. It, I guess, could still be done by one or multiple entities, but I think it is particularly different in the sense of its scope. It would be a much narrower range of validation activities that would be done under B is my interpretation of how we were trying ... again, no preference, but just trying to give you some choices here.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

I probably then mischaracterized it. B could actually be a modification of either A or C.

Mary Jo Deering – ONC – Senior Policy Advisor

That's correct. C applies to both A or B. In other words, either A or B could be done by one entity or multiple entities under when we saw broadly or narrowly defined.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

I'm actually going to contradict you there, Mary Jo.

Mary Jo Deering – ONC – Senior Policy Advisor

No, you're quite right. No, I misspoke. You are absolutely correct. I misspoke.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Yes, I think the choices are A. Here are the choices. One entity, multiple entities, broad validation versus high prioritization validation and accreditation.

Mary Jo Deering – ONC – Senior Policy Advisor

That's absolutely correct. You had it right the first time.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

I think it would be useful if we could characterize the three options according to the taxonomy John just articulated. So it's clear because the language that's there right now, I think, is easily confused.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

If we could perhaps have segmented the discussion, the first discussion is, should it be a one entity, or should we allow multiple entities under an umbrella?

John Mattison – Kaiser Permanente – Chief Medical Information Officer

My preference would be to have a single, overarching entity that could parse out the work under its supervision.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Okay. That's a little bit of the rephrasing of— Well, actually, that would be one with a little bit of a rephrasing. So it would be C, so one entity that could essentially subcontract the work.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Correct, and I'm thinking that's what Linda was suggesting with simplicity, but I'll ask Linda directly.

Linda Fischetti – VHA – Chief Health Informatics Officer

Yes. No, I like the idea of a single umbrella organization that can coordinate across all of the moving parts. Where there are problems, they can apply more effort. Where things are moving absolutely beautifully, they don't need to apply as much effort. So I like the umbrella entity, but the umbrella doesn't have to do all of the work.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

But if they were to parse it out, they would parse it out to one, for lack of a better term right now that I can think of, one subcontractor.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Not necessarily. I think the notion of the umbrella is that if you have multiple subcontractors, there has to be a clear, coordinated, centralized oversight so that there are not gaps or overlaps that become problematic.

Laura Adams – Rhode Island Quality Institute – President & CEO

I was thinking of this kind of along the lines of a certification of groups who have the authority to carry out the certification under the umbrella of the federal government. I was saying this sort of in the same way that there would be one umbrella organization and then there could be many carrying out the validation activity depending on how they would meet criteria to do that. But I saw more than one potentially.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Exactly.

W

Do we have an option that's one umbrella coordinating roles of different entities?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

We actually do because we've just said it, and then we'll just have to capture that, if that seems to me where everyone is going.

Mary Jo Deering – ONC – Senior Policy Advisor

Maybe I lost something. How is that different from A?

John Mattison – Kaiser Permanente – Chief Medical Information Officer

I think the language is imprecise. I think we're just clarifying the language and some ambiguity that was intended to separate A and C, but didn't effectively. I think what we're all agreeing on is a single, overarching entity that can subcontract out components of work to subcontractors.

Mary Jo Deering – ONC – Senior Policy Advisor

There's a difference between subcontractors and sub-accrediting bodies, so you would not like any sub-accrediting bodies to be recognized. There would be one accrediting entity, and it could just subcontract, or would it actually do it through sub-accreditation?

John Mattison – Kaiser Permanente – Chief Medical Information Officer

My preference would be subcontracting, not sub-accreditation. Laura, I'm curious on what your thoughts are on that.

Laura Adams – Rhode Island Quality Institute – President & CEO

Yes. I was actually thinking along the lines of sub-accreditation, that it would be delegated, and as long as those entities performed that function to a certain standard, there could be a number of them versus one place to get that done. Now I don't know how that fits with the simplicity concept. It might not, but it certainly opens up that activity to more than just one entity.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

Is that necessarily a distinction? In other words, could you subcontract more than one subcontractor to the same defined set of tasks, or does that require a sub-accreditation?

Laura Adams – Rhode Island Quality Institute – President & CEO

Good question.

W

John, when you first said the term subcontracting, I heard that as you were using it to be illustrative versus that this is the way the business process would work.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

That would be correct. What I hear us noodling around is that it seems like everyone starts off with an overarching validation authority. That validation authority may delegate that authority to an entity based upon identified need, and obviously capacity and capability.

John Mattison – Kaiser Permanente – Chief Medical Information Officer

If I could take a shot at maybe trying to summarize in a similar way, John, and that is that what we're saying is a couple things. First of all, we're recommending a single, overarching entity. Second of all, we would give them the authority to parse out the work. Third of all, we would allow them to parse out the same work to different subcontractors or sub-whatever you want to call them. Whether we call it contracting or accreditation, I'm not sure how important that distinction is, but I think what we're agreeing on is a single, overarching entity with the ability to parse the work and award work to more than one contractor within each parsed segment. Does that accurately reflect what other people were thinking and saying?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Let me suggest that. Would people be comfortable with that, because we've all been saying something a little bit differently? So it's an overarching authority that can parse out the work and the same work may be parsed out to more than one entity.

W

Do we need to get to that level of specificity?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Mary Jo, do we need to get to that specific?

Mary Jo Deering – ONC – Senior Policy Advisor

Probably not at this point. I think that as long as you clearly indicate whether you think this has to be totally unitary, and I think at least a strong consensus on an overarching validation authority with the ability to somehow— In fact, what I'm hearing is that you do not want that authority to unitarily perform all the work. Maybe that's one of the key distinctions too is that you see a value, or do you? I should put it in the form of a question. I'm hearing that you actually prefer that there be subcomponents, whatever the method be, through which some of the actual work gets performed.

M

To the question of whether it needs to be that specific or not, can we resolve that issue by using the word may, so the may parse it out, and they may have more than one process or entity perform each of the parsed tasks? So that what we're really arguing for, first and foremost, is coordination of this, and I think that's because of the ambiguity of boundaries of some of the work. What we want to do is not exclude the opportunity for it to be parsed out and allocated to more than one entity, but not necessarily to prescribe it. What we're essentially doing is not proscribing it, but neither are we prescribing how granular that has to be.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

I think that gets us there.

Michael Matthews – MedVirginia – CEO

Let's take it to the real world. We have exchange. We have participants in exchange. Is the validation responsibility here applying to be applied to exchange or to the participants in exchange? For example, let's say Med Virginia was not current in an HIE, but in fact was applying for membership. Does this process for validation apply to Med Virginia's participation as a member of an exchange, or if there is another exchange like entity that community that comes together to want to be part of the overall, under the umbrella of NW-HIN, is that the validation, or are we talking about both? I'll go ahead and be preemptive here. If we're talking about both then, to me, this usurps the very government's authority that is already established within exchange. So again, I will just appeal to the group to be clear about where this applies and where it does not apply.

Mary Jo Deering – ONC – Senior Policy Advisor

Michael, I was looking at the sub-bullets, the second and third one—they're not numbered—under A. I guess it's especially the second one, establishing equivalency criteria to recognize multiple pathways to validation as appropriate. I think it would be important to know whether the workgroup was now dropping that point under its new language because I think that that second bullet there was trying to get at what you just raised, or maybe not. You're not reading it that way.

Michael Matthews – MedVirginia – CEO

I'm not reading it that way. If it does, I guess I need some help with that.

Mary Jo Deering – ONC – Senior Policy Advisor

So you're actually getting more toward to whom does validation apply and who doesn't?

Michael Matthews – MedVirginia – CEO

Absolutely.

Mary Jo Deering – ONC – Senior Policy Advisor

And who is responsible for it.

Michael Matthews – MedVirginia – CEO

Yes because, again, we've been talking about devolution. To me, devolution in this case would be what is exchange's responsibility for its participants and members and how to shove that out versus having this NW-HIN authority leap over the governance mechanisms that are present with exchange to then have some kind of role of validation of the participants in exchange.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Right, but we've already, I think we dealt with that about 15 or 20 minutes ago when we said that if you have an entity that's an exchange implementation group, that the validation would apply to that implementation group. But there are certain circumstances, which we would expect a condition of participation to be flexible enough to address, which is an entity that doesn't, for whatever reason, doesn't have an exchange to be a part of or chooses not to be part of an exchange for whatever business reason.

Michael Matthews – MedVirginia – CEO

I'm good with that, John. We talked about it 15 or 20 minutes ago. The language that we're using on slide number 24, to me, is still not consistent with that. So if that prior conversation can then carry forward here

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Then we need to change this language here.

Mary Jo Deering – ONC – Senior Policy Advisor

So we can try to capture it, but I think that part of, in my mind, that second sub-bullet was getting rather to that in terms of recognizing multiple pathways to validation and getting equivalency to other groups. But anyway

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Yes. I think, Mary Jo, the reason why that's confusing is it's because if I'm a practice, and I'm part of an exchange, then I don't need to get validated through this mechanism as long as my exchange is validated.

Mary Jo Deering – ONC – Senior Policy Advisor

Right, right.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

So when we talk about equivalency as a pathway to validation, I think that's what twists it a little bit, and we can work on the language. Other comments? I think we have enough that we can send something out. Again, please take a look at all the slides now, and we'll be modifying the ones on validation based upon this conversation. Send e-mails to Mary Jo and myself and Mariann so we can pull all of this together and working towards what we need to present on Friday. At this point, I think it's time to see if there are any public comments.

Judy Sparrow – Office of the National Coordinator – Executive Director

Operator, can you check and see if anybody in the public wishes to make a comment?

Coordinator

We do not have any comments at this time.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Thank you so much. This has been a very rich conversation. It's been very helpful, hopefully. I remind everyone that we do have a call on Wednesday, and that please, if you've got comments, modifications, areas for clarification, please send it to me and to Mary Jo and Mariann so we can modify the document and enhance our discussion we'll have on Wednesday.

Michael Matthews – MedVirginia – CEO

John, a quick question from Michael before we close. How will the group be informed about the results of the discussion at 5:00 with the tiger team?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Mary Jo?

Mary Jo Deering – ONC – Senior Policy Advisor

Yes, I think we will certainly take that as an action item, and be sure and share it with the full workgroup.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

We will share it.

Michael Matthews – MedVirginia – CEO

Thank you.

Mary Jo Deering – ONC – Senior Policy Advisor

John Houston, are you still on the line? I was going to ask if John Houston wanted to join us since he's very knowledgeable about exactly what the tiger team is trying to do, but if not, I think we'll carry on.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Sure. Why don't you just shoot him an e-mail and let him know to get on, if he can?

Mary Jo Deering – ONC – Senior Policy Advisor

Okay.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Thank you, everyone.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Bye-bye.